



METAPHARMACEUTICAL

N DE LOTE:

0181223

29/12/2023



Kopran

Certificate Of Analysis
ATENOLOL EP

BATCH No.	: ALU/P2310025	ANALYTICAL REPORT No.	MFG. DATE : OCT.2023
DISPATCH QTY.	: 5.00 Kg	FPPA/231011	EXP. DATE : SEP.2028
SR. No.	TESTS	RESULTS	SPECIFICATIONS
1	APPEARANCE	White powder	White or almost white powder
2	SOLUBILITY	Complies	Sparingly soluble in water, soluble in anhydrous ethanol, slightly soluble in methylene chloride.
3	IDENTIFICATION A. Melting Point B. By IR C. By TLC	153.5°C Complies Complies	A. 152°C to 155°C B. Infrared absorption spectrum of sample is concordant to that of Atenolol Working Standard. C. The principle spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution
4	APPEARANCE OF SOLUTION	Clear and not more intensely coloured than intensity 6	Solution S is clear & not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour.
5	ANGLE OF OPTICAL ROTATION	+0.001°	-0.10° TO +0.10°
6	RELATED SUBSTANCES 1) Impurity B 2) Impurity F 3) Impurity G 4) Impurity I 5) Impurity J 6) Unspecified Impurity 7) Total Impurities	0.11 % BDL BDL BDL BDL BDL 0.11 %	NMT 0.2 % w/w NMT 0.15 % w/w NMT 0.15 % w/w NMT 0.15 % w/w NMT 0.15 % w/w NMT 0.10 % w/w NMT 0.5 % w/w
7	CHLORIDE	Complies	NMT 0.1 % w/w
8	SULPHATED ASH	0.07 %	NMT 0.1 % w/w
9	LOSS ON DRYING	0.25 %	NMT 0.5 % w/w
10	ASSAY ON DRIED BASIS	99.8 %	99.0 % to 101.0 % of C ₁₄ H ₂₂ N ₂ O ₃

THIS PRODUCT CONFORMS TO EP

This batch is in conformity with EP & provisions of certificate of suitability R1-CEP 1998-017-Rev 06
Granted to Kopran.

DATE: 28/11/2023

PREPARED BY	CHECKED BY	APPROVED BY
 28/11/2023 C. C. Belose Sr. Officer - QA	 28/11/2023 A. B. Lagad Asst. Manager - QC	 28/11/2023 P.M. Sheth AGM - QC

C.O.A. issued to : M/s. F. & A. Pharma - Handels - GmbH, Germany.

Date of Sampling - 28th October 2023Date of Analysis - 16th November 2023

KOPRAN RESEARCH LABORATORIES LIMITED

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